



IND 55,984
NDA 21-226
NDA 21-251

Abbott Laboratories
Attention: Rebecca A. Welch
100 Abbott Park Road
D-491, AP6B-1SW
Abbott Park, Illinois 60064-6108

Dear Ms. Welch:

Reference is made to FDA's March 31, 1999 Written Request for pediatric studies for ABT-378.

We are amending the below listed section of the Written Request. All other terms stated in our Written Request issued on March 31, 1999 remain the same.

Timeframe for submitting reports of the studies:

On or before July 1, 2004.

Reports of the studies should be submitted as **a new drug application or as a supplement to an approved NDA** with the proposed labeling changes you believe would be warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED**" in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. Please also send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, please submit proposed changes and the reasons for the proposed changes to your application. Submissions of proposed changes to this request should be clearly marked "**PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES**" in large font, bolded type at the beginning of the cover letter of the submission. You will be notified in writing if any changes to this Written Request are agreed upon by the Agency.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits in the pediatric population.

If you have any questions, contact Mr. Sean J. Belouin, R.Ph., Regulatory Project Manager, at 301-827-2335.

Sincerely yours,

{See appended electronic signature page}

Dianne Murphy, M.D.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Dianne Murphy
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